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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/750,456	12/28/2000	Glenn Friedrich	LEX-0156-USA	6650

7590 04/08/2003

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,456	FRIEDRICH ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The amendment filed January 27, 2003 (Paper No. 13) has been entered. Claims 1 and 7 have been amended.

Claims 1-7 are pending in the instant application.

Applicant's election without traverse of Group 393, Claims 1-7 in Paper No. 13 is acknowledged. The elected invention is drawn to cells comprising a mutation in a gene comprising the nucleotide sequence set forth in SEQ ID NO: 393.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Although the specification contains a reference to the prior applications it does not specify the relationship between the nonprovisional applications.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claims are drawn to a genetically engineered mammalian cell that has been mutated by a process comprising the insertion of a recombinantly manipulated polynucleotide sequence into a gene in said genetically engineered mammalian cell wherein said gene is identifiable as corresponding to SEQ ID NO: 393.

The specification discloses that the claimed cells can be used to produce mutant animals capable of germline transmission of the mutated gene (page 1, lines 23-26). The specification further discloses that the mutated cells and animals are used to investigate and define the cellular and biological functions of the mutated gene (page 13, lines 17-19). However, neither the specification as-filed nor any art of record discloses or suggests any specific property for the cells or the animals that would be produced from the mutated cells such that a utility would be well-established for the cells. Furthermore the specification does not teach a specific asserted utility for the mutated cells because any mutant ES cell can be used to produce mutant animals and therefore this does not constitute a **specific** utility for cells carrying the particular mutation recited in the claims. A **specific** utility is one that is specific to the subject matter claimed. This contrasts with a **general** utility that would be applicable to the broad class of the invention. The contemplated uses of the animals that would be generated from the mutant cells is unspecified. The disclosure generally contemplates that the mutated cells or animals could be used as disease models or in assays for compounds or genes that compensate for the mutant phenotype and which can then be used to treat diseases and disorders related to the observed phenotype (page 15, lines 1-6). However, the disclosure does not specify the mutant phenotype or any specific disease that would be modelled by the cells or animals. Thus, the asserted utility to use the mutated cells to produce mutant animals as disease models lacks specificity. Moreover, with regard to using the cells or animals produced from the cells to investigate and define the cellular and biological functions of the mutated gene, use of a product to further study the product itself does not define a "real world" context of use and thus does not represent a specific and substantial asserted utility. The utility of generally using the mutated cells or

animals produced from the cells to investigate the function of the mutated gene does not define a "real world" context of use but would require or constitute further research to reasonably identify or confirm such a context of use. A utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility. The research contemplated is unspecified. Thus, the asserted utility to study gene function lacks specificity.

Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility cannot be assessed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite in their recitation of "wherein said gene is identifiable as corresponding to SEQ ID NO: 393" because it is unclear what would constitute a gene "corresponding to" SEQ ID NO: 393.

Claims 4-6 are indefinite in their recitation of "wherein said polynucleotide sequence is present on a viral vector because Claim 1 already requires that the polynucleotide sequence be inserted into the chromosome of the cell.

Claim 7 is indefinite in its recitation of "encoding SEQ ID NO: 393" because SEQ ID NO: 393 is a DNA nucleotide sequence, not an amino acid sequence, and therefore the polynucleotide sequence can not "encode" SEQ ID NO: 393.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER